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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/763,989	01/22/2004	Gary Berg	P-4998.03	8234
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MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MS-LC340 MINNEAPOLIS, MN 55432-5604				
EXAMINER EVANISKO, GEORGE ROBERT				
ART UNIT		PAPER NUMBER		
3762				

DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/763,989	Applicant(s) BERG ET AL	
	Examiner George R. Evanisko	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 10, “a first threshold” and “a second threshold” are vague since it can not be determined if this is referring to the amplitude of the signal or the threshold at which the patients tissue is stimulated.

In claim 3, “the...pulses” lack antecedent basis.

Claims 18 and 19 are vague since they are directed to the “system” of claim 10 and since claim 10 is a “method” claim. In addition, in claim 18, “the second electrical pulses” lacks antecedent basis. Claims 18 and 19 also appear to be the same as claim 20.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 9, 10, 14, 16-20 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sholder et al (5899928). Sholder discusses the use of a magnet and reed switch to trigger generation of the second stimulation pulses in column 11. In addition, Sholder shows in Figure 7C the use of a second threshold signal, 330-340, that is below the first threshold signal, since the second threshold signal occurs during the refractory period and will not be above the patients stimulation threshold and cause stimulation. In addition, Sholder provides device and patient data with the second signal (column 13). Finally, Sholder teaches the use of amplitude modulation, frequency modulation (pulse number or interval modulation), and pulse width modulation in column 5.

In the alternative, Sholder discloses the claimed invention except for the second subthreshold signal being below the first signal (i.e. a smaller amplitude). It would have been

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obvious to one having ordinary skill in the art at the time the invention was made to modify the communication system as taught by Sholder, with the second signal being subthreshold and below the first signal since it was known in the art that implantable communication systems use the second signal to be smaller and subthreshold compared to the first stimulation signal, to provide communication signals that are below the stimulation threshold and that do not cause any ill effects and are safe to the patient.

Claims 2-8, 11-13, and 15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sholder et al.

Sholder discloses the claimed invention except for the signals being biphasic (claims 2 and 11) and therefore include circuitry to control the polarity of the pulse (claim 8) and the signal including marker channel information (claim 15). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the implantable system as taught by Sholder, with the signals being biphasic and the signal including marker channel information since it was known in the art that implantable systems use signals that are biphasic (and therefore include circuitry to control the polarity of the pulse) to provide no net charge to the electrode/body and/or prevent the electrode from degrading and since it was known to provide the internal communicated signal with marker channel information to allow the physician to verify the proper operation of the implanted device.

In addition, to the pulse frequency (pulse number or interval) modulation presented in the 102/103 rejection above, Sholder discloses the claimed invention using pulse number or pulse interval modulation except he doesn't disclose (call it) pulse frequency modulation. It would have been obvious to one having ordinary skill in the art at the time the invention was made to

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modify the implantable system as taught by Sholder, with the use of pulse frequency modulation since it was known in the art that implantable systems use pulse frequency modulation for communication of data to provide a conventional communication protocol that is easily understood, received, and processed by conventional circuitry.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-20 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 of U.S. Patent No. 6704602. Although the conflicting claims are not identical, they are not patentably distinct from each other because the patented claims are more narrow and meet the limitations of the broader application claims. In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the patented claims the pulses being biphasic, the external device triggering the internal pulse generator, and the transmitted data to be marker channel, electrogram, or device data since it was known in the art that implantable stimulators use the pulse being biphasic to provide a charge balanced pulse, the external device triggering the internal device so the internal device only delivers the data when necessary to prevent power

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loss, and the transmitted data to be marker channel, electrogram, or device data to allow the physician to verify the device is operating properly.


Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Funke is one example of many showing the use of the second signal being subthreshold and below the first signal.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R. Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


George R Evanisko
Primary Examiner
Art Unit 3762

7/10/5

GRE
July 10, 2005